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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/555,727

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Jon Christian Soper

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EXAMINER

CHAWLA, JYOTI

ART UNIT

PAPER NUMBER

1794

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/555,727	Applicant(s) SOPER ET AL.	
	Examiner JYOTI CHAWLA	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/7/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-20 are pending and examined in the current application.

Claim Objections

Claim 9 is objected to because of the following informalities: spelling of “colouring matter” are not acceptable US spellings. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(1) Claim 1-5, 8,10-12, 15-16 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Cherukuri et al (US 5266335), hereinafter Cherukuri.

Cherukuri teaches of Matrix particles comprising a discontinuous phase of a plurality of inclusions of oil, wherein the oil is optionally flavor oil or fragrance oil (Column 4, lines 16-21), the oil dispersed within a matrix, the matrix comprising a cross-linked polymer, i.e., gelatin and gluteraldehyde (a cross-linking agent) (Column 6, lines 64-65) and at least one filler, for example, gum arabic (Column 3, lines 20-35). Cherukuri further teaches that encapsulated flavors may be formulated in effective amounts with conventional additives, such as pharmaceutically acceptable carriers or confectionery ingredients (Column 7, lines 45-50), i.e., pharmaceutical carriers can also be added as fillers to the encapsulated flavor matrix. Regarding claims 2-3, Cherukuri further teaches that polymer (or colloidal material) “may be selected from a group consisting of natural and synthetic colloidal materials such as gelatin, albumen, alginates, casein,

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agar-agar, starch, pectins, gum arabic, carboxymethyl cellulose, polyacrylic acid, polyacrylamide, and the like, and mixtures thereof”, which includes alginates and pectins (Column 6, lines 27-35), as claimed.

Regarding claim 4, Cherukuri teaches of matrix particles comprising a filler selected from the group consisting of inorganic substances, organic substances, and combinations thereof (i.e., gum arabic or pharmaceutical carriers or food ingredients used as carriers disclosed in Column 3, lines 20-35 and Column 7, lines 45-50), as is instantly claimed.

Regarding claims 5, 15 and 16, Cherukuri teaches a matrix comprising a filler, e.g., gum arabic, which is added to equal parts of polymer, i.e., gelatin (Column 7, lines 19-21), i.e., filler in a ratio of about 1:1 to the polymer, which falls in applicants ranges for claims 5, 15 and 16.

Regarding claim 8, Cherukuri teaches of matrix particles that comprise coating of gelatin and gum arabic (Column 3, lines 20-35 and Column 7, lines 17-18), i.e., the matrix comprising at least one coating.

Regarding claim 10, Cherukuri teaches of products (chewing gums and confections, Column 8, lines 39-47) comprising matrix particles.

Cherukuri teaches of encapsulated flavor matrix as recited in claim 1 and as recited in claim 11 (See Column 7, lines 10-45 and Column 20, line 20 to Column 21, line 10).

Regarding the method of making the matrix as recited in claim 11, it is noted that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

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Regarding claim 12, Cherukuri teaches that polymer (or colloidal material) “may be selected from a group consisting of natural and synthetic colloidal materials such as gelatin, albumen, alginates, casein, agar-agar, starch, pectins, gum arabic, carboxymethyl cellulose, polyacrylic acid, polacrylamide, and the like, and mixtures thereof”, (Column 6, lines 27-35), which includes carboxymethyl cellulose, i.e., cellulose polymers or derivatives as claimed.

Regarding claim 20, Cherukuri teaches of matrix particles comprising flavor oils and combinations thereof and gums and colloids, i.e., carriers, coating agents (column 4, lines 16-68, Column 6, lines 27-35), i.e., at least one of an active ingredient. Cherukuri also teaches of addition of emulsifiers or stabilizers to the flavor oil comprising matrix (Column 5, line 58 to Column 6, line 5), as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

(A) Claims 7, 13-14, 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherukuri (US 5266335).

Cherukuri has been applied to claims 1-5, 8, 10-12, 15-16 and 20 under 35 USC 102(b) in the office action above.

Cherukuri teaches of matrix particles comprising flavor oil (Column 4, lines 16-21), a cross-linked polymer, i.e., gelatin and gluteraldehyde (a cross-linking agent) (Column 6, lines 64-65) and at least one filler, i.e., gum arabic (Column 3, lines 20-35) for adding to foods and pharmaceuticals (Column 8, lines 39-47). Cherukuri further teaches that encapsulated flavors may be formulated in effective amounts with conventional additives, such as pharmaceutically acceptable carriers or confectionery ingredients (Column 7, lines 45-50), i.e., addition of pharmaceutical or food carriers or bulking agents as fillers to the encapsulated flavor matrix was known at the time of the invention, as taught by Cherukuri.

Regarding bulking agents or carriers as disclosed in claims 13 and 14, Cherukuri teaches of "bulking agents such as mineral adjuvants which may serve as fillers and textural agents. Useful mineral adjuvants include calcium carbonate, magnesium carbonate, alumina, aluminum hydroxide, aluminum silicate, talc, tricalcium phosphate, dicalcium phosphate, and the like, and mixtures thereof." (Column 11, line 65 to Column

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12, line 10), which include carbonates and silicates as recited in claims 13 and 14.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to further include one or more of the bulking agents as taught by Cherukuri, to the matrix comprising flavor oil and a cross-linked polymer at least for the purpose of providing bulk or texture to the matrix. One would have been further motivated to add one or more of specific fillers which are most suited for the intended use of the encapsulated oil comprising matrix.

Regarding the surface oil as recited in claims 7, 17-19, applicant has defined surface oil as "By "surface oil" is meant an undesirable concentration of oil occurring at the surface of particles" (Specification, Page 1, lines 25-26) and ""Surface oil" is the weight percent of the sample that is oil which may be extracted from the sample by a simple solvent wash of the sample in a reagent that is non-intrusive to the sample matrix particles." (Specification, Page 2, lines 5-8).

Regarding the surface oil, Cherukuri teaches of encapsulated flavor oil material with colloidal material including fillers, as recited in claim 1. Regarding the surface oil, Cherukuri teaches that the size of the pores in the walls of microcapsules may be controlled by the rate of gelling process, such that if the emulsion is rapidly cooled and gelled the resulting matrix of microcapsules will have a pore size so small that the encapsulated oil will not escape through the capsule walls (Column 6, line 65 to Column 7, line 5). Cherukuri also teaches that after the particles are made, water and anticaking agent are added and the microcapsules are washed 4 times, filtered and then dried (Column 21, lines 1-8). Thus, Cherukuri teaches of making the microcapsules as recited in claim 1 and in a manner such that no oil escapes and the surface oil is removed with the help of water and anticaking agent, i.e., no surface oil. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that Cherukuri teaches of no or low surface oil. One of ordinary skill would have been motivated to modify Cherukuri and disclose the amount of surface oil at least for the purpose of quantifying the level of excess oil contained in the matrix. One would have been further motivated to quantify the amount of surface oil in an encapsulated matrix at the time of

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preparation and several times during storage to determine the storage stability of the matrix comprising the flavor oil.

Further, it is noted that the applicant has described the product with parameters and equations which cannot be measured by the office for prior art comparison, because the office is not equipped to manufacture prior art products and compare them for patentability purposes. Therefore, as a prima facie case of obviousness has been properly established, the burden is shifted to the applicant to show that the prior art product is different.

(B) Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cherukuri, in view of Huzinec et al (US 5912030), hereinafter Huzinec.

Cherukuri has been applied to claims 1-5, 8, 10-12,15-16 and 20 under 35 USC 102(b) in the office action above.

Regarding claim 6, Cherukuri teaches that matrix particles comprise colloidal material which includes one or more polymers (or colloidal material) "may be selected from a group consisting of natural and synthetic colloidal materials such as gelatin, albumen, alginates, casein, agar-agar, starch, pectins, gum arabic, carboxymethyl cellulose, polyacrylic acid, polyacrylamide, and the like, and mixtures thereof", which includes alginates and pectins (Column 6, lines 27-35). Cherukuri is silent as to the matrix particles comprising microcrystalline cellulose as filler. Huzinec teaches of microcrystalline carrier material, including microcrystalline cellulose (Column 2, lines 15-19) which can be mixed with additives, such as, flavors, flavor enhancers, flavor masking additives, sweeteners, sweetener enhancers, vitamins, pharmaceuticals, minerals, colors, acids, and mixtures thereof and also for encapsulated additives (Column 2, lines 32-40 and Column 3, lines 38, 54-58). Huzinec also teaches that the carrier, such as, Microcrystalline cellulose (MCC) has a property where more than one additives can be added to the carrier and each additive can be released either at the same time or at different times (Column 2, lines 8-13). Further it is noted that MCC works as a filler, binder, and flow aid and anticaking agent and as suspension stabilizer,

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and emulsifier (Dictionary of Food Ingredients). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Cherukuri in view of Huzinec and add microcrystalline cellulose to the matrix comprising the encapsulated flavor. One of ordinary skill would have been motivated to modify Cherukuri at least for the purpose of producing an encapsulated flavor matrix comprising one or more encapsulated active ingredient or oil/ flavor oils wherein the matrix particles remain stable and have a delayed release property.

(C) Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cherukuri, in view of Merritt et al (US 4515769), hereinafter Merritt.

Cherukuri has been applied to claims 1-5, 8, 10-12, 15-16 and 20 under 35 USC 102(b) in the office action above

Regarding claim 9, Cherukuri teaches of matrix particles comprising flavor oil (Column 4, lines 16-21), a cross-linked polymer, i.e., gelatin and gluteraldehyde (a cross-linking agent) (Column 6, lines 64-65) and at least one filler, i.e., gum arabic (Column 3, lines 20-35) for adding to foods and pharmaceuticals (Column 8, lines 39-47). Cherukuri is silent as to the matrix particles comprising coloring matter. Merritt teaches of encapsulated flavorant material comprising coloring material (Column 11, lines 17-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Cherukuri in view of Merritt and add color to the encapsulated flavor. One of ordinary skill would have been motivated to modify Cherukuri at least for the purpose of producing an encapsulated flavor and a composition containing such flavor with interesting appearance (Merritt Column 11, line 18-20).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

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are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 1, 4, 8 and 11 of current application 10/555727 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6 of U.S. Patent No. 6325951 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are addressed to flavor oil encapsulation in a matrix of colloids.

2) Claims 1-4, 6, 8, 10-12 of current application 10/555727 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 6, 9, 11, 12, 13, 16, 20, 21, 23-25 and 28 of U.S. Patent No. 6106875. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are addressed to flavor oil encapsulation product and method of making such a product comprising a matrix of colloids or gels (polymers) that may be proteins (alginate or gelatin) carbohydrate (cellulose and cellulose derivatives).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTI CHAWLA whose telephone number is (571)272-8212. The examiner can normally be reached on 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McNeil can be reached on (571) 272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JC/
Examiner
Art Unit 1794

/JENNIFER MCNEIL/
Supervisory Patent Examiner, Art Unit 1794